K122971

7. Summary of Safety and Effectiveness

OCT 25 2012

"510(K) SUMMARY"

Submitted By/
Contact Person: Dr. Benjamin Reinmann
Vice President
Quality Management & Regulatory Affairs
Ypsomed AG
Brunnmattstrasse 6
CH - 3401 Burgdorf
Switzerland
Tel. 0041-344244111
Fax 0041-344244122
E-mail: benjamin.reinmann@ypsomed.com

Date Prepared: September 24, 2012

7.1 Trade/Proprietary Name: Clickfine Pen Needle

7.2 Common/Usual Name: Injection Pen Needle

7.3 Classification Name: Hypodermic single lumen needle

7.4 Classification: FDA has classified Hypodermic single lumen needles in Class II. Final Order was published in the Federal Register on October 21, 1980 after review by the General Hospital and Personal Use Devices Classification Panel.

CFR Reference: 880.5570 Procode: FMI

7.5 Purpose of Submission: To expand the product line to include smaller needles including a 4 mm, 32 gauge needle.

7.6 Substantial Equivalence: The Ypsomed Clickfine Pen Needles are substantially equivalent to the Clickfine Pen Needles (K102108). The equivalence is supported by the attached documentation.

7.7 Device Description
The Ypsomed Clickfine Pen Needles are sterile, non-pyrogenic, single use needles designed to be used with commercially available pen-injectors for the administration of prescribed fluids. Each needle is individually packaged in a sealed protective container with a peel tab. The pen needles are used by peeling back the peel tab and snapping or screwing the hub onto the threaded end of the pen injector. The back end of the cannula punctures the rubber injection port of the drug reservoir in the pen-injector. The outer protective cap is then removed. The inner protective cap will remain over the needle until the drug is ready to be injected. When the injection is

needed, the inner protective cap is removed and the needle is inserted into the chosen site. The pen-injector automatically delivers the fluid through the needle. The protective cap is replaced and the needle is then removed, safely discarded and replaced with a new needle.

7.8 Intended Use

The intended use of the modified device remains the same as the predicate device Clickfine Pen Needles (K102108):
The Ypsomed Clickfine Pen Needles are intended for the hypodermic injection of fluids into the body when attached to an injection pen.

7.9 Technological Characteristics

The technological characteristics have not changed.

7.10 Performance and Safety Data

Ypsomed has performed the relevant assessments specified in the following international and internal standards and protocols and confirmed compliance of the modified devices and equivalence to the predicate devices.
The Clickfine Pen Needles have met the requirements of the relevant sections of the following standards:

- ISO 11608-2:2012 Needle based injection systems for medical use – Requirements and test methods – Part 2: Needles
- ISO 9626:1991/Amd.1:2001 Stainless steel needle tubing for the manufacture of medical devices
- ISO 7864:1993 Sterile hypodermic needles for single use

The verifications have shown evidence that the Clickfine Pen Needles meet the acceptance criteria of these standards. Based on the results it can be concluded that the device performance and safety are acceptable for the product.

7.11 Conclusion

Ypsomed AG concludes based on the information presented that the modified product is substantially equivalent to the current product legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 25 2012

P/L Biomedical
Mr. Lee Leichter
10882 Stonigton Avenue
Fort Myers, Florida 33913

Re: K122971
Trade/Device Name: Clickfine Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 24, 2012
Received: September 26, 2012

Dear Mr. Leichter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122971

Device Name: Clickfine Pen Needle

Indications For Use: The Clickfine pen needle is intended for the hypodermic injection of fluids into the body when attached to an injection pen.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/26/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122971